



<b>FORM PTO-1229/A and B (modified PTO/SB/08)</b> <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/783,020		ATTY. DOCKET NO.: A0870.70000US00	
				FILING DATE: February 23, 2004		CONFIRMATION NO.: 3753	
				APPLICANT: Collins et al.			
				GROUP ART UNIT: 1651		EXAMINER: Vera Afremova	
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#### U.S. PATENT DOCUMENTS

Examiner's Initials <sup>#</sup>	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
VA	A15	2002-0006432	A1	Collins et al.	01-17-2002
VA	A16	2003-0170217	A1	Collins et al.	09-11-2003
VA	A17	2003-0215467	A1	Collins et al.	11-20-2003

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials <sup>#</sup>	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials <sup>#</sup>	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
VA	C152	Yildirim et al., "Characterization and antimicrobial spectrum of bifidocin B, a bacteriocin produced by Bifidobacterium bifidum NCFB 1454," J Food Prot, 61(1):47-51, (1998). Abstract Only.	

EXAMINER: <i>V. Afremova</i>	DATE CONSIDERED: <i>8-10-2006</i>
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\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

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filed on 6/12/2006

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✓A	A1	4,347,240		Mutai et al.	08-31-1982
↑	A2	4,435,389		Mutai et al.	03-06-1984
	A3	5,032,399		Gorbach et al.	07-16-1991
	A4	5,443,826		Borody	08-22-1995
	A5	5,711,977		Yang et al.	01-27-1998
	A6	5,834,423		Koketsu et al.	11-10-1998
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	A10	6,132,710		Panigraphi et al.	10-17-2000
	A11	6,368,591		Chen et al.	04-09-2002
	A12	6,645,530		Borody	11-11-2003
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		Office/ Country	Number	Kind Code			
✓A	B1	EP	0 384 319	B1	VISKASE CORPORATION	04-28-1999	
↑	B2	EP	0 508 701	B1	QUEST INTERNATIONAL B.V.	07-10-1996	
	B3	EP	0 904 784	A1	N.V. NUTRICIA	03-31-1999	
	B4	EP	1 312 667	A1	WAKAMOTO PHARMACEUTICAL CO., LTD.	05-21-2003	
	B5	GB	1 503 094		NISSHIN FLOUR MILLING CO. LTD.	03-08-1978	
	B6	JP	9241173		WAKAMOTO PHARMACEUT CO.	09-16-1997	Y-Abstract
	B7	RU	2 091 075	C1	GNII GENETIKI I SELEKTSII PROM	09-27-1997	Y-Abstract
	B8	RU	2 109 054	C1	MOSKOVSKIJ	04-20-1998	Y-Abstract
✓A	B9	WO	89/05849	A1	CHR. HANSEN'S LABORATORIUM	06-29-1989	
	B10	WO	90/01335	A1	THOMAS BORODY	02-22-1990	

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✓	B11	WO	90/09398	A1	BIOINVENT INTERNATIONAL AB	08-23-1990	
✓	B12	WO	97/35596	A1	ABBOTT LABORATORIES	10-02-1997	
✓	B13	WO	98/00035	A1	CAVALIERE VED. VESELY	01-08-1998	
✓	B14	WO	98/35014	A2	FORBAIRT TRADINGS AS BIORESEARCH IRELAND	08-13-1998	
✓	B15	WO	99/51631	A1	KORHONEN	10-14-1999	
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**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
✓	C1	Adachi, Susumu, "Lactic Acid Bacteria and the Control of Tumours," The Lactic Acid Bacteria, 1:233-261, (1992).	
✓	C2	Anand et al., "Antibacterial Activity Associated with Bifidobacterium bifidum - II," Cult. Dairy Prod, pages 21-23, (1985). (Attached copy is missing 1 page)	
✓	C3	Arai et al., "Cytokines: Coordinators of Immune and Inflammatory Responses," Annual Rev. Biochem., 59:783-836, (1990).	
✓	C4	Aranda et al., "Analysis of Intestinal Lymphocytes in Mouse Colitis Mediated by Transfer of CD4 <sup>+</sup> , CD45RB <sup>high</sup> T Cells to SCID Recipients <sup>1</sup> ," Jour. of Immunology, 158(7):3464-3473, (1997).	
✓	C5	Arihara, et al., "Salivacin 140, a novel bacteriocin from Lactobacillus salivarius subsp. salicinius T140 active against pathogenic bacteria," Letters in Applied Microbiology, 22:420-424, (1996).	
✓	C6	Bachwich, et al., "Tumor Necrosis Factor Stimulates Interleukin-1 and Prostaglandin E <sub>2</sub> Production in Resting Macrophages," Biochemical and Biophysical Res. Comm., 136(1):94-101, (1986).	
✓	C7	Blum et al., "Adhesion studies for probiotics: need for validation and refinement," Trends in Food Science & Technology, 10:405-410 (1999).	
✓	C8	Bouhnik et al., "Effects of Bifidobacterium sp fermented milk ingested with or without inulin on colonic bifidobacteria and enzymatic activities in healthy humans," Eur. Jour. Clin. Nut., 50:269-273, (1996).	
✓	C9	Bouhnik et al., "Survie et effets chez l'homme des bactéries ingérées dans less laits fermentés," LAIT, 73:241-247, (1993).	Y-Abstract
✓	C10	Brandtzaeg et al., "Immunopathology of human inflammatory bowel disease," Springer Semin Immunopath, 18:555-589, (1997).	
✓	C11	Brink et al., "Antimicrobial activity of lactobacilli: preliminary characteristization and optimization of production of acidocin B a novel bacteriocin produced by Lactobacillus acidophilus M," Jour. of Applied Bacteriology, 77:140-148, (1994).	
✓	C12	Brzuszcak et al., "Cyclic AMP-dependent anion secretion in human small and large intestine," Jour. of Gastroenterology and Hepatology, 11:804-810, (1996).	

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VA	C13	Charteris et al., "Antibiotic susceptibility of potentially probiotic Bifidobacterium isolates from the human gastrointestinal tract," Letters in Applied Microbiology, 26:333-337, (1998).	
↑	C14	Charteris et al., "Selective detection, enumeration and identification of potentially probiotic Lactobacillus and Bifidobacterium species in mixed bacterial populations," Int. Jour. of Food Microbiology, 35:1-27, (1997).	
	C15	Charteris, et al., "Antibiotic Susceptibility of Potentially Probiotic Lactobacillus Species," Jour. Food Protection, 61(12):1636-1643, (1998).	
	C16	Charteris, et al., "Development and application of an in vitro methodology to determine the transit tolerance of potentially probiotic Lactobacillus and Bifidobacterium species in the upper human gastrointestinal tract," Jour. of Applied Microbiology, 84:759-768, (1998).	
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	C18	Chevalier et al., "Detection of Bifidobacterium species by enzymatic methods," Jour. of Appl. Bacteriology, 68:619-624, (1990).	
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	C20	Collins et al., "A Controlled Trial of Probiotic Treatment of IL-10 Knockout Mice," Gastroenterology, 116(4):1 page, (1999). Abstract G2981.	
	C21	Collins et al., "Demonstration of Probiotic Function in a Double Blind Placebo Controlled Clinical Trials in Adults," Functional Food Research in Europe, pages 40-41, (1998).	
	C22	Collins et al., "Probiotics and Man – The Host Microbe Interface," Gastroenterology, 116(4):1 page, (1999). Abstract G2982.	
	C23	Collins et al., "Selection of Probiotic Strains for Human Applications," Int. Dairy Journal, 8:487-490, (1998).	
	C24	Collins, "Probiotic Lactobacilli-Towards Defining Selection and Functional Criteria," Demonstration Fair CT96-1028, Page 27, (1996).	
	C25	Collins, "Selection of Probiotic Strains and Potential Therapeutic Applications," Book of Abstracts from Eur. Comm. Biotech and Fair Prog., page L-2, (1995).	
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	C27	Collins, J.K., "Probiotics and Inflammatory Bowel Disease: Animal Models," Functional Food Research in Europe, page 124, (1998).	
	C28	Cong et al., "Genes, Bacteria, and T Cells: Ingredients for Inflammatory Bowel Disease," Gastroenterology, 115:1595-1596, (1998). (Summary by Shanahan, O'Sullivan, and Collins)	
	C29	Crabbe et al., "The Normal Microbial Flora as a Major Stimulus for Proliferation of Plasma Cells Synthesizing IgA in the Gut," Int. Arch. Allergy 34:362-375, (1968).	
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	C31	Darveau, Richard, "Infection, inflammation, and cancer," Nature Biotechnology, 17:19, (1999).	

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✓	C32	Dawson et al., "18 pH, buffers, and physiological media," Data For Biochemical Research, pages 417-448, (1969).	
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	C34	Dinareello et al., "New Concepts on the Pathogenesis of Fever," Reviews of Infectious Diseases, 10(1):168-189, (1988).	
	C35	Donnelly, et al., "Differential Regulation of IL-1 Production in Human Monocytes by IFN-γ and IL-4," Journal of Immunology, 145(2):569-575, (1990).	
	C36	Dunne et al., "Epithelial Adhesion of Probiotic Microorganisms in vitro and in vivo," Gastroenterology, 116(4):1 page, (1999). Abstract G3058.	
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	C38	Favier et al., "Fecal β-D-Galactosidase Production and Bifidobacteria Are Decreased in Crohn's Disease," Digestive Diseases and Sci., 42(4):817-822, (1997).	
	C39	Feency et al., "Lack of Specific Systemic Immune Response on Oral Consumption of Probiotic Lactobacilli," Int. Dairy Journal, 8(5/6):1 page, (1998).	
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	C41	Flynn et al., "Isolation and Characterisation of the Novel Antibacterial Proteins, ABP-1 and ABP-118 from Human Isolates Lactobacillus salivarius subsp. salivarius UCC-1 and UCC-118," Intl. Dairy Jour., 8(5/6):1 page, (1998).	
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	C43	Gahan et al., "Innate resistance to Listeria monocytogenes in tumor-bearing mice," Jour. of Leukocyte Biology, 62:726-732, (1997).	
	C44	Ganguly et al., "Mechanism of action of cholera toxin & other toxins," Indian J. Med. Res., 104:28-37, (1996).	
	C45	Gardiner et al., "Characterisation of Cheddar Cheese Harboring Probiotic Lactobacillus Adjuncts," Int. Dairy Journal, 8(5/6):597, (1998).	
	C46	Gardiner et al., "Cheddar Cheese as a Probiotic Delivery System," Sixth Symposium on Lactic Acid Bacteria, Abstract J28, (1999).	
	C47	Gardiner et al., "Evaluation of Cheddar Cheese as a Food Carrier for Delivery of a Probiotic Strain to the Gastrointestinal Tract," J. Dairy Sci., 82:1379-1387, (1999).	
	C48	Gardiner et al., "Influence of a Probiotic Adjunct Culture of Enterococcus faecium on the Quality of Cheddar Cheese," J. Agric. Food Chem., 47:4907-4916, (1999).	
	C49	Gardiner et al., "Preparation of Spray Dried Powders Harboring High Levels of Probiotic Lactobacilli," Sixth Symp. on Lactic Acid Bacteria, Abstract J29, (1999).	
✓	C50	Gardiner, et al., "Development of a Probiotic Cheddar Cheese Containing Human-Derived Lactobacillus paracasei Strains," Applied and Env. Microbiology, pages 2192-2199, (1998).	

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✓A	C51	Gatanaga et al., "Purification and characterization of an inhibitor (soluble tumor necrosis factor receptor) for tumor necrosis factor and lymphotoxin obtained from the serum ultrafiltrates of human cancer patients," Proc. Natl. Acad. Sci, 87:8781-8784, (1990).	
1	C52	Gibson, Glenn, "Dietary modulation of the human gut microflora using prebiotics," Jour. of Nutrition, 80(2):S209-S212, (1998).	
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	C55	Groot, J.A., "Correlation between electrophysiological phenomena and transport of macromolecules in intestinal epithelium," The Veterinary Quarterly, 20(3):S45-S49, (1998).	
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	C57	Henderson et al., "Cytokines, homeostasis, networks and disease," Bacteria-Cytokine Interactions in Health and Disease, pages 79-130, (1998).	
	C58	Houde et al., "Treatment of Acute Enteritis with Oral Administration of Short-Term High-Dose Bifidobacteria," Chinese Jour of Microecology, 6(6):47, (1994).	Y
	C59	Huis et al., "Establishing a scientific basis for probiotic R&D," 12:6-8, (1994).	
	C60	Inagaki et al., "Causes of Death in Cancer Patients," Cancer, 33(2):568-573, (1974).	
	C61	Isolauri et al., "Oral Bacteriotherapy for Viral Gastroenteritis," Digestive Diseases and Sciences, 39(12):2595-2600, (1994).	
	C62	Jinggang, Lan, "Immunopotentiating Activity of Bifidobacterium and Its Significance," For. Med. Sci., Clinic Biochem & Med Test, 19(5):231-233, (1998).	Y
	C63	Jong, S.C., "Probiotics for Humans and Animals," ATCC Quarterly Newsletter, 13(1):1-4, (1993).	
	C64	Kagnoff, "Immunology of the Intestinal Tract," Gastroenterology, 105:1275-1280, (1993).	
	C65	Kato et al., "Suppressive Effects of the Oral Administration of Lactobacillus Casei on Type II Collagen-Induced Arthritis in DBA/1 Mice," Life Sciences, 63(8):635-644, (1998).	
	C66	Kawakami et al., "A Group of Bactericidal Factors Conserved by Vertebrates For More Than 300 Million Years," Journal of Immunology, 132(5):2578-2581, (1984).	
	C67	Kim et al., "The Properties of Bifidobacteria Isolated from Korean," Korean Journal of Dairy Science, 20(3):191-204, (1998).	Y-Abstract
	C68	Kim, Hyung, "Characterization of Lactobacilli and Bifidobacteria as applied to Dietary Adjuncts <sup>1</sup> ," Cultured Dairy Products Journal, pages 6-9, (1988).	
	C69	Klaenhammer, Todd, "Genetics of bacteriocins produced by lactic acid bacteria," FEMS Microbiology Rev., 12:39-86, (1993).	
	C70	Kühn, et al., "Interleukin-10-Deficient Mice Develop Chronic Enterocolitis," Cell, 75:263-274, (1993).	
✓A	C71	Kulkarni et al., "Inhibitory Effect of Bifidobacterium longum Cultures on the Azoxymethane-Induced Aberrant Crypt Foci Formation and Fecal Bacterial $\beta$ -Glucuronidase," Proc. Soc. Experim. Biol. Med., 207:278-283, (1994).	

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✓	C72	Lamm et al., "Interaction of antigens and antibodies at mucosal surfaces," Ann Rev Microbiol, 51:311-40, (1997). (Previously cited as Ramos et al.)	
✓	C73	Lee et al., "The coming of age of probiotics," Trends in Food Science & Technology," 6:241-245, (1995).	
	C74	Legrand-Defretin et al., "Ion-Pair High-Performance Liquid Chromatography of Bile Salt Conjugates: Application to Pig Bile," LIPIDS, 26(8):578-583, (1991).	
	C75	Leonard, et al., "Regulation of the Inflammatory Response in Animal Models of Multiple Sclerosis by Interleukin-12," Critical Reviews in Immunology, 17:545-553, (1997).	
	C76	Lucey et al., "Developing Fields in Food Biotechnology," Food Science and Technology, 11(4):230-233, (1997).	
	C77	Madsen et al., " <i>Lactobacillus SP</i> prevents development of enterocolitis in interleukin-10 gene deficient mice," Gastroenterology, 112(4):1030, (1997).	
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	C81	Mattila-Sandholm, "Novel Methods for Probiotic Research," Demonstration Project Fair2 CT96-1028, Pages 11-15, (1997).	
	C82	Mattila-Sandholm, et al., "Probiotics: towards demonstrating efficacy," Trends in Food Sci & Tech., 10:393-399, (1999).	
	C83	McBrearty et al., "Probiotic Bifidobacteria and Their Identification Using Molecular Genetic Techniques," Proc. of British Nutritional Foundation, pages 97-107, (2000).	
	C84	McCracken, et al., "Probiotics and the Immune System," Probiotics a Critical Review, pages 85-113, (1999).	
	C85	McFarland, et al., "Pharmaceutical Probiotics for the Treatment of Anaerobic and Other Infections," Anaerobe, 3:73-78 (1997).	
	C86	McGee et al., "A synergistic relationship between TNF- $\alpha$ , IL-1 $\beta$ , and TGF- $\beta$ 1 on IL-6 secretion by the IEC-6 intestinal epithelial cell line," Immunology, 86:6-11, (1995).	
	C87	Medaglini et al., "Mucosal and systemic immune responses to a recombinant protein expressed on the surface of the oral commensal bacterium <i>Streptococcus gordonii</i> after oral colonization," Proc. Natl. Acad. Sci, 92:6868-6872, (1995).	
	C88	Mestan et al., "Antiviral effects of recombinant tumour necrosis factor <i>in vitro</i> ." Nature. 323:816-819, (1986). (Previously cited as Wong et al.)	
✓	C89	Morrisey et al., "Election of a Probiotic Strain to Modify Human Gut Flora and a Controlled Trial of Delivery and Efficacy," Ir. Soc. of Gastroenterology, 167(8):7, (1998).	
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*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE If Appropriate)
<u>VA</u>	AA 4435389	03/06/84	Mutai et al	424	181	
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ATTY. DOCKET NO.: P66879US3  
 SERIAL NO.: 10/783020  
 APPLICANT(S): COLLINS

GROUP ART UNIT: 1651  
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